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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,956	01/29/2001	Michele Bennett Kinrade	U 013223-9	9691

7590 10/29/2003

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EXAMINER	
WEGERT, SANDRA L	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/29/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,956	KINRADE ET AL.	
	Examin r	Art Unit	
	Sandra Wegert	1647	

-- Th MAILING DATE of this communication app ars on th cover sh et with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-90* is/are pending in the application.

4a) Of the above claim(s) *10-90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed 26 June 2003 has been entered. Claims 10-90 are withdrawn by the examiner. Claims 1-9 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office action.

Withdrawn Objections and/or Rejections

URL's

The objection to the specification because it contained browser-executable code as set forth at p. 3 of the previous Office Action (24 March 2003) is *withdrawn* in view of the amendment which removed all hypertext links from the disclosure (17 July 2003).

Maintained Objections and/or Rejections

35 USC § 112, first paragraph - Written Description

The rejection of Claims 1-9 for lack of Written Description, as set forth at p. 3-5 of the previous Office Action (24 March 2003), is *maintained.* In the response of 24 June 2003, Applicants arguments generally followed two lines of reasoning: 1) "The issue raised having regard to the written description requirement is essentially one as to the proper scope of the claim[s] in light of the disclosure" (page 4, 26 June 2003), citing the case of Amgen, Inc. v.

Hoechst Marion Roussel, 65 USPQ 2d 1385; and, 2) "a functional definition of a claim feature should be permissible [based on the disclosure and the number of representative species provided]" (page 5, last paragraph and paraphrasing page 6, last paragraph). Applicants cited several cases important to the interpretation of the Written Description statute: Amgen, Inc. v. Hoechst Marion Roussel, Inc; Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561, 19 USPQ 2d 1111, 1115 (Fed. Cir. 1991); Regents of University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); Enzo Biochem, Inc., v. Gen-Probe, Inc., 296 F.3d 1316, 63 USPQ 2d 1609 (Fed. Cir.2002); Wertheim, 541 F 2d, 257, 262 (CCPA 1976) and Gentry Gallery v. Berkline 45 USPQ 2d 1498.

Applicant's arguments filed 26 June 2003 have been fully considered but are not found persuasive for the following reasons:

The case of Wertheim, 541 F 2d, 257, 262 (CCPA 1976) concerned the burden on the Examiner when interpreting claims for Written Description. Its conclusion was essentially that "whether the description requirement is met must be determined on a case-by-case basis and is a question of fact." It gave little specific information on how to examine receptor proteins for adequate written description. As for the case, Gentry Gallery v. Berkline, it was an important case in terms of refining Written Description requirements for mechanical devices, such as reclining chairs, but sheds little light on examination of receptor proteins.

The fact patterns found in each additional case cited by the applicant are different than those applied by the examiner in the previous Office action. In *Amgen, Inc. v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc,* the product being discussed was DNA, which necessarily cannot be described in the same way as the peptides in Claims 1-9 of the instant

Application (for example, a deposit cannot be made of the peptides alone to satisfy Written Description). Furthermore, particularly in the case of *Amgen, Inc. v. Hoechst Marion Roussel, Inc.* many issues were discussed in determining whether one patent infringed another; foremost among these were enablement, as well as the definiteness of the language used in the Amgen patent. In *Vas-Cath Inc. v. Mahurkar* it was found, as the applicant states: that "the written description requirement is intended to define the invention with some specificity to prevent a patentee from later expanding the scope of his patent. It requires the patentee must "recount his invention in such detail that his future claims can be determined to be encompassed within his original creation," which statement the examiner agrees with. It is simply not known at this point which receptors fall within the scope of the receptor defined in Claims 1-9. This is particularly relevant since the two receptors that appear to be the "*NPY5ΔY1C*" receptors specified in the claims (Table 1) display very different Kd's and Bmax's, illustrating that the receptor, as defined, does not describe a single genus.

Applicants cite *Eli Lilly* (*Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997)) to support the argument that "common structural features" can be used to describe a protein genus. The Federal Register (2001, Vol. 66, No. 4, page 1100) makes clear that *Eli Lilly* must be considered when an application is directed to a gene for a *known* protein (e.g., Preproinsulin); it makes no mention of fusion-proteins or chimeric proteins like those in the instant Application. The patent at issue in *Eli Lilly* contained claims to recombinant plasmids comprising cDNA encoding insulin from several animal species. The specification disclosed the entire cDNA sequences for proinsulin and preproinsulin of rats; it did not disclose "the human, mammalian, and other vertebrate" cDNA sequences. The court concluded that the claims for

human, mammalian, and vertebrate cDNA sequence claims were invalid because the patent did not provide adequate written description to support those claims. The court explained that claims directed to genetic material required language that distinguished the claimed material from others: "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." In other words, a patent claiming DNA required the precise definition of the DNA sequence itself. A "mere recitation of its function or a reference to a potential method for isolating will does not suffice." These results- if they can be applied to polypeptides, which is doubtful- would seem to support the Written Description rejection found in the last Office Action (24 March 2003).

Applicants then discussed claim scope, stating: "the court is backing away from the interpretation that some have put on its earlier decisions arguing that only limited scope is permissible in the field of biotechnology" (page 5, 26 June 2003), citing the latest Amgen case.

However, In *Amgen, Inc. v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003), the details of infringement discussed by the Federal Circuit considered the issues of written description and enablement of claims to a polynucleotide encoding a single fully-described polypeptide. In that case, Amgen alleged that Hoechst infringed the Amgen patent for DNA encoding erythropoietin. The court held that some of Amgen's claims were invalid for lack of a written description and enablement and some were not. However, the fact patterns in the Amgen case are quite different from those in the instant Application, since that case involved a polynucleotide of known sequence, encoding a polypeptide of exact sequence.

35 U.S.C. § 112, first paragraph- Enablement.

Claims 1-9 are rejected under 35 U.S.C. 112, as lacking enablement. The reasons for this rejection are set forth at pp. 5-8 of the previous Office Action (26 June 2003).

Claims 1-9 are directed to an "*NPY5ΔY1C*" NPY receptor protein, comprised of 15 separate segments of the formula: *NPY5 receptor N-terminal extracellular domain- first transmembrane domain –first intracellular loop domain, - second transmembrane domain, etc.*

The specification teaches the polypeptide of SEQ ID NO: 9. However, the specification does not teach functional or structural characteristics of the chimeric NPY receptor polypeptide genus *as recited in the claims*. Furthermore, it is not obvious from a general description of the chimeric NPY receptor what the precise functional characteristics of the receptor might be. There are two receptors disclosed in the Specification that may be considered *NPY5ΔY1C* receptors. Since the two receptors display very different Kd's and Bmax's, it is not obvious from the general description given in claims 1-9 what the function of a receptor is when defined by the terms used (e.g., *NPY5 receptor N-terminal extracellular domain- first transmembrane domain –first intracellular loop domain, - second transmembrane domain, etc*), illustrating that the receptor, as defined, does not possess a single function.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to determine an activity or property of the claimed protein such that it can be determined how to use the chimeric receptor as claimed and to screen for activity, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to several representative species of the genus

claimed, the complex nature of the invention, the state of the prior art establishing that biological activity cannot be predicted based on a structural description and the unpredictability of the effects of mutation on protein structure and function, as well as the breadth of the claims which fail to recite particular biological activities -- undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

The Applicant further argues that: "each polypeptide comprises all fifteen specific domains in the recited order" and "[t]hose of ordinary skill in the art could readily make the chimeras of the present invention, and use them in assays of receptor binding and/or function" (page 7, 26 June 2003).

However, there is a lack of guidance in the Specification and the prior art as to exactly what structure is required for the protein variants encompassed by Claims 1-9. Applicant's arguments that the domains are listed in the proper order and one could merely test for activity is not sufficient for an enabling disclosure. Additionally, the Specification fails to teach *which* activity is possessed by the NPY chimeric receptor as claimed, since two probable examples of *NPY5ΔY1C* from the specification possess different binding characteristics.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW
16 October 2003

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER